

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COVIDIEN LP
Petitioner

v.

ETHICON ENDO-SURGERY, INC.
Patent Owner

Case IPR2013-00209
Patent 8,317,070

Before SALLY C. MEDLEY, JOSIAH C. COCKS, and
GEORGIANNA W. BRADEN, *Administrative Patent Judges*.

BRADEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. Background

Covidien LP (“Petitioner”) filed a Petition (Paper 1, “Pet.”) on March 25, 2013, requesting *inter partes* review of claims 1-14 of U.S. Patent No.8,317,070 (Ex. 1001, “the ’070 patent”) pursuant to 35 U.S.C. §§ 311-319. On August 26, 2013, we granted the Petition, and instituted this *inter partes* review of claims 1-14 on fewer than all of the grounds of unpatentability alleged. Paper 7, “Dec. to Inst.”. After institution of trial, the Patent Owner, Ethicon Endo-Surgery, Inc. (“Patent Owner”), filed a Patent Owner Response (Paper 17, “Resp.”) to the Petition. Petitioner filed a Reply (Paper 21) to the Patent Owner Response.

Counsel for both Petitioner and Patent Owner were present and presented argument at an oral hearing held on April 10, 2014.¹

The Board has jurisdiction under 35 U.S.C. § 6(c). In this final written decision, issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73, we determine Petitioner has shown by a preponderance of the evidence that all challenged claims are unpatentable under 35 U.S.C. § 103.

B. The ’070 Patent

The ’070 patent discloses surgical stapling devices that are “capable of producing staples of different formed lengths” when the staples are applied, for instance, to tissue. (Ex. 1001, Abstract; col. 2, ll. 28-30.) According to the ’070 patent:

Whenever a transection of tissue is across an area of varied tissue composition, it would be advantageous for the

¹ A transcript of the oral hearing is included in the record. Paper 28.

staples that are closest to the cut line to have one formed height that is less than the formed height of those staples that are farthest from the cut line. In practice, the rows of inside staples serve to provide a hemostatic barrier, while the outside rows of staples with larger formed heights provide a cinching effect where the tissue transitions from the tightly compressed hemostatic section to the non-compressed adjacent section.

Id. at col. 2, ll. 4-12. The '070 patent further discloses the use of staples with two prongs that extend from the main portion of the staple body, as shown in Figure 81, reproduced below. *Id.* at col. 27, ll. 57-58; Figures 81, 93.

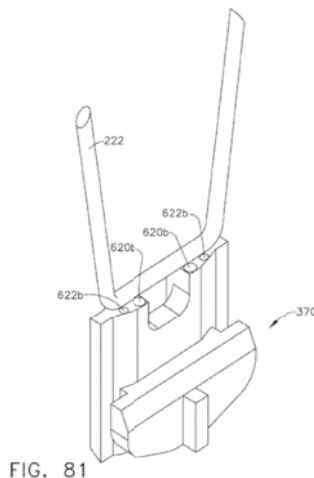


Figure 81 illustrates an embodiment of a staple with two prongs that extend from the main portion of the staple body.

Claims 1 and 8 are the only independent claims in the '070 patent and are reproduced below (some paragraphing added):

1. A surgical stapling device comprising an end effector that comprises:

a circular anvil having a staple forming surface;

a plurality of staples facing the staple forming surface of the anvil, each staple comprising a main portion and two prongs, wherein the two prongs each comprise a first end and a second end, wherein the first ends are connected to opposite ends of the main portion, and wherein the two prongs extend non-parallelly from the main portion; and

a staple driver assembly comprising a plurality of staple drivers, wherein each staple driver supports one of the plurality of staples and is configured such that, when the staple driver assembly is actuated, each staple driver drives the staple into the staple forming surface of the anvil,

wherein a first quantity of the staples have a first pre-deformation height, measured from a lower surface of the main portion to the second end of the first prong, and a second quantity of the staples have a second pre-deformation height, measured from a lower surface of the main portion to the second end of the first prong,

wherein the first height is less than the second height, such that when the staple driver assembly is actuated, the first quantity of staples have a different formed staple length than the second quantity of staples.

8. A surgical stapling device comprising:

a non-pivotable anvil having a staple forming surface; and

a staple cartridge facing the anvil, wherein the staple cartridge comprises:

a plurality of staples facing the staple forming surface of the anvil, each staple comprising a main portion and two prongs, wherein the two prongs each comprise a first end and a second end, wherein the first ends are connected to opposite ends of the main portion, and wherein the two prongs extend non-parallelly from the main portion; and

a plurality of staple drivers, wherein each staple driver supports one of the plurality of staples and is configured such that, when the staple drivers are actuated, each staple driver drives the staple into the staple forming surface of the anvil,

wherein a first quantity of the staples have a first pre-deformation height, measured from a lower surface of the main portion to the second end of the first prong, and a second quantity of the staples have a second pre-deformation height, measured from a lower surface of the main portion to the second end of the first prong,

wherein the first height is less than the second height, such that when the staple driver assembly is actuated, the first quantity of staples have a different formed staple length than the second quantity of staples.

C. Prior Art References Alleged to Support Unpatentability

The following table summarizes the prior art references asserted in the instituted grounds:

Name	Description	Date	Exhibit
Pruitt	US 4,941,623	July 17, 1990	Ex. 1003
Viola	International Publ. No. WO 2003/094747 A1	Nov. 20, 2003	Ex. 1004
Burdorff	US 5,697,543	Dec. 16, 1997	Ex. 1005
Conta	US 4,304,236	Dec. 8, 1981	Ex. 1006
Green	US 3,494,533	Feb. 10, 1970	Ex. 1009

D. Grounds of Unpatentability Instituted

The following table summarizes the challenges to patentability that were instituted for *inter partes* review:

Claim	Grounds	Reference(s)
Claim 1-5, 7, 8, and 10-13	§ 103	Viola and Green
Claim 6, 11, and 14	§ 103	Viola, Green, and Pruitt
Claim 9	§ 103	Viola, Green, and Burdorff
Claim 8 and 10-14	§ 103	Pruitt and Green
Claim 9	§ 103	Pruitt, Green, and Burdorff
Claims 1-7	§ 103	Pruitt, Green, and Conta

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Claim terms also are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech, Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

If an inventor acts as his or her own lexicographer, the definition must be set forth in the specification with reasonable clarity, deliberateness, and

precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998). Neither Petitioner nor Patent Owner contends that the Specification of the '070 patent, as filed, coined a new meaning for any term, different from the ordinary recognized meaning for any term.

1. *“two prongs extend non-parallelly from the main portion”*

The phrase “two prongs extend non-parallelly from the main portion,” which is recited in both independent claims, was construed initially for purposes of the Decision to Institute to mean that the extension of two prongs of a staple are non-parallel relative to each other in extending from the main portion of the staple. Dec. to Inst. 7-9; *see also* Decision on Petitioner's Request for Rehearing, Paper 10. Petitioner asserts that the Specification for the '070 patent does not support such a construction, because nowhere in the patent is there a description of staples with two prongs that are non-parallel relative to each other. Petitioner's Request for Rehearing, Paper 9; Tr. 6-7. However, we reject Petitioner's position and find that Figures 81 (reproduced *supra*) and 93 of the '070 patent illustrate staples with non-parallel legs. Therefore, we are not persuaded that a change in claim construction from that issued in the Decision to Institute is merited.

2. *“formed staple length”*

Each of claims 1 and 8 requires a plurality of staples identifiable as a “first quantity” of staples having a “first pre-deformation height” and a “second quantity” having a “second pre-deformation height.” Those claims further recite that “when the staple driver assembly is actuated, the first quantity of staples have a different formed staple length than the second quantity of staples.”

The terms “height” and “length” are understood generally as being terms that are not necessarily the same in designating measurements of a given structure. However, as discussed in the Decision to Institute, those terms are used throughout the Specification of the ’070 patent to designate the same dimension in connection with the extension of prongs of a staple. Dec. to Inst. 9-10. For instance, prongs 225 shown in Figure 12 are designated as having a “length ‘P’,” which is the dimension of the prongs extending from the main portion 223. Ex. 1001, col. 11, ll. 20-22; *see also* col. 16, ll. 14-16 (describing “prong lengths ‘P’”). Elsewhere in the Specification, the dimension “P” for the prongs is designated “prong heights.” *Id.* at 19, ll. 25-26. Similarly, in connection with “formed staples” the terms “formed lengths” and “formed heights” are each used in reference to the extension of the prongs from the main portion of the staple after it has been formed. *E.g., id.* at col. 2, ll. 39-44; col. 16, ll. 54-64; col. 19; ll. 65-67. Accordingly, as set forth in the Decision to Institute, in the context of the ’070 patent, the “formed staple length” is understood as referencing the distance or “height” that the prongs extend from the main portion of the staple when the staple is formed.

3. “*non-pivotable anvil*”

Independent claim 8 includes recitation of a “non-pivotable anvil.” As is understood from the ’070 patent, an “anvil” is a structure having a surface against which staples are driven or fired so as to configure the staple into a “form[ed]” condition. Ex. 1001, Abstract; col. 1, ll. 45-58.

In the Decision to Institute, we determined that the broadest reasonable interpretation consistent with the Specification of the ’070 patent is an anvil that does not rotate or swing about a short rod or shaft. Dec. to

Inst. 11. During the course of the trial, neither party challenged our construction of the claim term. Therefore, we see no reason to alter the construction set forth in the Decision to Institute.

B. Claims 1-14 – Alleged Obviousness over Viola, Pruitt, and/or Green

Petitioner asserts that claims 1-14 of the '070 patent are unpatentable under 35 U.S.C. § 103(a) over the prior art, specifically arguing that the claims are unpatentable over various combinations of Viola, Pruitt, and/or Green. Pet. 4-5, 58-59. “Section 103(a) [of 35 U.S.C.] forbids issuance of a patent when ‘the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.’” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). To establish obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *See CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003); *In re Royka*, 490 F.2d 981, 985 (CCPA 1974).

Patent Owner disputes Petitioner’s contention that the challenged claims would have been obvious. According to Patent Owner, the prior art fails to teach all of the limitations of the claims, and, specifically, “Viola fails to disclose staples with multiple *formed* heights as required by all claims of the ‘070 Patent.” Resp. 10. However, Patent Owner’s argument is contradictory to Patent Owner’s characterization of Viola in a proceeding before the European Patent Office. *See, e.g.*, Reply 4; Ex. 1024 at 1; Ex. 1025 at 2; Ex. 1026; Ex. 1027 at 2. Furthermore, during the oral hearing, counsel for Patent Owner admitted that all the recited elements of the patent claims are found in the asserted prior art. Tr. 23-24. Given Patent

Owner's admission regarding the prior art, there is no factual dispute that the cited references teach all of the recited elements.

Despite the teaching of all the claim elements in the prior art, Patent Owner maintains that one of skill in the art would not have arrived at the claimed subject matter, because (1) there was no reason to combine the cited prior art references, and (2) the prior art teaches away from the claimed invention. Resp. 21; Tr. 23-24, 26-27. Petitioner argues, to the contrary, that non-parallel staples were well-known in the art, and it would have been obvious to try such staples with the staple devices of Viola or Pruitt. Pet. 58. According to Petitioner, combining non-parallel staples with the staple devices of Viola or Pruitt would have constituted the mere substitution of one known element for another, and would have yielded predictable results. *Id.*

1. Reason to Combine Teachings of the Prior Art

In making an obviousness determination, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 550 U.S. at 418. Patent Owner contends that "the evidence fail[s] to show a specific reason why one of ordinary skill in the art would have combined Green with Viola or Pruitt to arrive at the claimed invention." Resp. 21. However, Petitioner argues that one of skill in the art would have been motivated to modify the staple devices of Viola and Pruitt to use Green's staples with non-parallel or "outwardly flaring" legs in order to securely hold staples within corresponding retention slots of a staple cartridge. Pet. 59 (citing Ex. 1009 at col. 13, l. 71-col. 14, l. 4 and Ex. 1010 ¶ 108).

Contrary to Petitioner's argument, Patent Owner contends there are multiple problems with using non-parallel staples, and any benefit bestowed by retaining staples in a staple cartridge would be outweighed by "the overall undesirability of non-parallel staples." Resp. 38. Mr. Ortiz, expert for Patent Owner, testified that alternative methods existed for retaining staples in a staple cartridge (Ex. 2004 ¶¶ 76-78), so one of skill in the art would not have to rely on non-parallel legs to ensure that staples do not fall out of a staple cartridge. However, Mr. Ortiz testified he had not used the alternative methods he opined on (Ex. 1023 at 72, ll. 11-14 and 64, ll. 19-21); rather, Mr. Ortiz used non-parallel staples "maybe 50 or 75 percent of the time" in his practice (*id.* at 56, ll. 10-15). Mr. Bolanos, expert for Petitioner, testified about the reasons why a skilled artisan would have used staples with non-parallel legs, and stated that he routinely used such staples in his practice. Ex. 1010 ¶ 108; Ex. 1031 ¶ 4-5. Additionally, Mr. Kelly, an expert for Patent Owner in a lawsuit in Germany, testified that the "problem of keeping staples in their pockets is generally solved . . . by bending the tips of the legs of the unloaded staples slightly outward," i.e., having staple legs that are non-parallel. Ex. 1033 at 2.

According to Petitioner, the testimony of Mr. Ortiz and Mr. Kelly contradict Patent Owner's contention that non-parallel staples were not beneficial and would not have been used by one of skill in the art. Reply 6. We agree with Petitioner and find that Patent Owner's evidence is entitled to less weight than Petitioner's evidence as to this issue. Although Mr. Ortiz originally testified that one of ordinary skill in the art would not have been motivated to use staples having non-parallel legs (Ex. 2004 ¶¶ 75, 79, 88), he also testified later, under cross-examination, that he himself used non-

parallel staples in practice a majority of the time (Ex. 1023 at 56, ll. 10-15). We find his testimony to be less persuasive than Petitioner's expert testimony of Mr. Bolanos, especially in light of the testimony by Mr. Kelly in the German lawsuit that the "problem of keeping staples in their pockets is generally solved . . . by bending the tips of the legs of the unloaded staples slightly outward," i.e., by having staple legs that are non-parallel. For all of these reasons, Petitioner has shown, with supporting evidence, that one of skill in the art would have had reason to combine the prior art to arrive at the claimed invention.

2. *Teach Away from the Claimed Invention*

A reference does not teach away if it merely expresses a general preference for an alternative invention, but does not "criticize, discredit, or otherwise discourage" investigation into the claimed invention. *DePuy Spine Inc. v. Medtronic Sofamor Danek*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)). "[I]n general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

Patent Owner contends that one of skill in the art would have been led away from using non-parallel staples as disclosed by Green, because (1) surgical staplers need precise alignment of staples (Resp. 23-32), and (2) additional force is required to fire non-parallel staples (*id.* 32-38).

Petitioner argues, to the contrary, that the use of non-parallel staples may involve factors such as alignment and force, but such factors would have been understood by those skilled in the art. Reply at 8. According to

Mr. Bolanos, expert for Petitioner, alignment and the proper application of force were considerations commonly taken into account when designing staplers. Ex. 1031 ¶ 7. Furthermore, Mr. Ortiz, Patent Owner's expert, testified later, under cross-examination, that the alignment and force analysis he described in his declaration were known to one of skill in the art. *See, e.g.*, Ex. 1023 at 142:22-143:4, 126:17-127:6, 136:24-137:18.

Therefore, we are not persuaded by Patent Owner's argument that certain attributes of non-parallel staples (such as ensuring precise alignment and requiring additional force) would dissuade one of ordinary skill in the art from using such staples. Patent Owner has not directed us to where in Viola or Pruitt there is the suggestion that use of staples with non-parallel legs was unlikely to work. Although Viola and Pruitt do not teach the use of staples with non-parallel legs, the references do not teach away from the use of staples with non-parallel legs. Moreover, Patent Owner has not rebutted Petitioner's showing by demonstrating that the disclosures in Viola, Pruitt, or Green would have led one of ordinary skill in the art to conclude that Green's non-parallel staples were unsuitable for use in the Viola or Pruitt stapling devices.

Therefore, we reject Patent Owner's argument that a skilled artisan would not have found it obvious to use staples with non-parallel legs with staple devices of Viola or Pruitt because the prior art teaches away from the claimed invention.

3. Obvious to Try Known and Predictable Elements in the Prior Art such as Staples with Non-Parallel Legs

In *KSR*, 550 U.S. at 421, the Supreme Court explained that "obvious to try" may apply when "there are a finite number of identified, predictable

solutions” to a known problem. The Court explained that when the path has been identified and “leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” *Id.* The Federal Circuit elaborated that the identified path must “present a finite (and small in the context of the art) number of options easily traversed to show obviousness.” *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F. 3d 1358, 1364 (Fed. Cir. 2008).

Petitioner contends that one of skill in the art would have understood that the devices in Pruitt and Viola could use, or be modified to use, staples with non-parallel legs. Pet. 58; Ex. 1010 ¶ 108. According to Petitioner, staples with non-parallel legs were well known at the time of the alleged invention of the '070 patent (Pet. 58-59), and, in fact, practitioners in the field had the limited option of using staples with parallel legs or non-parallel legs (Tr. 4-5; Reply 6 (citing Ex. 1032 at 50)). Patent Owner contends that the use of non-parallel staples was not obvious. According to Patent Owner, if the use of non-parallel staples was obvious, then Petitioner would have used them prior to the filing of the '070 patent, and would have advertised their use of such staples. Resp. 43-44; Tr. 21-23. Patent Owner also contends that the prior art would have discussed the use of non-parallel staples. Tr. 21-23.

First, “[i]n many fields there may be little discussion of obvious techniques or combinations, and market demand, rather than scientific literature, may often drive design trends.” *KSR*, 550 U.S. at 402. Thus, we give little weight to the absence of advertising by Petitioner of its use of non-parallel staples.

Second, as disclosed in Green, the prior art does discuss the use of non-parallel staples. Ex. 1009. That disclosure is inconsistent with the position taken by Patent Owner that such staples were not known to be used.

Finally, as discussed above, Mr. Ortiz used non-parallel staples “maybe 50 or 75 percent of the time” in his practice (Ex. 1023 at 56, ll. 10-15). Mr. Bolanos, expert for Petitioner, worked for Petitioner and testified that when designing staplers he started with a design premised on non-parallel staples. Ex. 1031 ¶ 4. The testimony of the experts indicates that those of skill in the art knew of non-parallel staples and frequently used such staples. Furthermore, Patent Owner’s expert witness testified in a German lawsuit that a person skilled in the art knew that he could choose between two different staple shapes, namely between U-shaped or parallel staples on the one hand, and V-shaped or non-parallel staples, on the other. Reply 6 (citing Ex. 1032 at 50).

Therefore, given the prevalence of non-parallel staples, and the fact that those in the field had but two choices for staple designs, we find it would have been obvious to try non-parallel staples when designing stapling devices, such as those disclosed in Viola and Pruitt. Additionally, the limited choice of two staple designs further supports our finding that a person of skill in the art would have had reason to combine the non-parallel staple of Green with the stapling devices in Viola and Pruitt.

C. Secondary Considerations of Non-Obviousness

Patent Owner contends that Petitioner has failed to meet its burden of showing unpatentability, because the objective indicia of nonobviousness indicate that the claimed subject matter would not have been obvious. Resp. 48-59; Tr. 29. Objective indicia constitute independent evidence of non-

obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966) (holding that tactual inquiries for an obviousness determination include secondary considerations based on evaluation and crediting of objective evidence of nonobviousness); *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012). Notwithstanding what the teachings of the prior art would have suggested to one with ordinary skill in the art at the time of Patent Owner's invention, the totality of the evidence submitted, including objective evidence of nonobviousness, may lead to a conclusion that the claimed invention would not have been obvious to one with ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471-1472 (Fed. Cir. 1984).

Secondary consideration factors include (1) unexpected results, (2) commercial success, (3) satisfaction of long-felt need, (4) failure of others, and (5) copying by others. *E.g.*, *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 291 (Fed. Cir. 1985); *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894 (Fed. Cir. 1984). Patent Owner has alleged (1) commercial success, and (2) satisfaction of long-felt but unresolved need. Resp. 48-59. However, as discussed below, the objective indicia argued by Patent Owner do not establish a nexus with the claimed subject matter.

There must be a demonstrated "nexus" between the merits of the claimed invention and the evidence of secondary considerations before that evidence is accorded substantial weight in an obviousness determination. *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575 (Fed. Cir. 1984); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983); *see also In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996); *In re Fielder*, 471 F.2d 640, 642 (CCPA 1973). "Nexus" is a legally and

factually sufficient connection between the objective evidence and the claimed invention, such that the objective evidence should be considered in determining nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). In the absence of an established nexus with the claimed invention, secondary consideration factors, such as commercial success and satisfaction of a long-felt but unresolved need, are not entitled to much, if any, weight, and generally have no bearing on the legal issue of obviousness. *See In re Vamco Machine & Tool, Inc.*, 752 F.2d 1564, 1577 (Fed. Cir. 1985).

1. Commercial Success of Petitioner's Tri-Staple Devices

Patent Owner argues that the commercial success of Petitioner's Tri-Staple devices establishes the requisite nexus with the claims of the '070 patent, and indicates the non-obviousness of the claims. Resp. 52. Specifically, Patent Owner contends that high sales volume of the Tri-Staple products can be mapped to the practice of at least claims 8 and 10 of the '070 patent. *Id.*; Ex. 2004 ¶¶ 130-131. When the patent is said to cover a feature or component of a product, Patent Owner has the burden of showing that the commercial success derives from the feature, in this case use of non-parallel staples and staples of different preformed and formed heights. *See Tokai Corp. v. Easton Enters., Inc.*, 632 F. 3d 1358, 1369 (Fed. Cir. 2011). In other words, in order to establish a proper nexus, Patent Owner must offer proof that the sales were a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter. *See In re Huang*, 100 F. 3d 135, 140 (Fed. Cir. 1996). Furthermore, if commercial success is due to an element in the prior art, no nexus exists. *Ormco Corp. v. Align Tech.*,

Inc., 463 F.3d 1299, 1312 (Fed. Cir. 2006); *see also Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed.Cir.1983) (holding claimed invention obvious where patent holder “failed to show that such commercial success . . . was due to anything disclosed in the patent in suit which was not readily available in the prior art”).

In arguing for commercial success, Patent Owner relies heavily on marketing material and a 2012 Annual Report to Shareholders from Petitioner that describe Petitioner’s Tri-Staple devices and tout the devices as being some of the most successful products for Petitioner. Resp. 55 (citing Ex. 2013, Ex. 2016, Ex. 2019, Ex. 2020, and Ex. 2024). Patent Owner compares the sales for the Tri-Staple devices to products Petitioner previously offered for sale (Petitioner’s “legacy devices”), and argues, directing attention to evidence, that as sales for the Tri-Staple devices increased, sales for the legacy devices decreased. *Id.* at 56-57. According to Patent Owner, the evidence shows that Petitioner charges a premium for the Tri-Staple devices compared to the legacy products, and despite the higher price, Petitioner now sells more of the Tri-Staple devices than it sells of the legacy devices. *Id.* at 56.

Patent Owner’s expert, Mr. Ortiz, testified that he examined Petitioner’s Tri-Staple device, and based on his examination, declared that the device practiced the invention of at least claims 8 and 10 of the ’070 patent. Ex. 2004 ¶ 130. Mr. Ortiz also testified that he analyzed how the Tri-Staple devices compared to the legacy products and “under[stood] that the Covidien legacy devices did not include all of the following features in one device: non-parallel staples with multiple pre-formed heights which, when fired, resulted in staples with multiple formed heights.” *Id.* at ¶ 136.

However, Mr. Ortiz did not testify that he examined Petitioner's legacy products. According to Mr. Ortiz, "the combination of features [of claims 8 and 10 of the '070 patent] results in a 'truly innovative surgical stapling platform' that Covidien has priced at a premium compared to devices not containing the combination of the patented features." *Id.* at ¶ 140. Patent Owner, thus, concludes that the increased sales for the Tri-Staple devices over the legacy devices is "due to the fact that the [Tri-Staple] devices contain the combination of features in claims 8 and 10 of the '070 Patent." Resp. 57; Ex. 2004 ¶ 140.

Petitioner contends, to the contrary, that the commercial success of the Tri-Staple devices is attributable to unclaimed features, such as ergonomic design, precise articulation, and reloads that provide simpler selection and reduced inventory. Reply 15. Therefore, according to Petitioner, any success enjoyed by the Tri-Staple devices is not due to the claimed invention. Tr. 46.

We have considered Patent Owner's Exhibits 2016, 2019, 2020, and 2024, which purport to show that the Tri-Staple devices include the features of claims 1-14. We also have reviewed the testimony of Mr. Ortiz at Exhibit 2004 in detail. First, Patent Owner has not shown sufficient credible evidence that the sales of the Tri-Staple devices are the result of the claimed invention, rather than other features of the Tri-Staple devices. Second, as Patent Owner admitted, all of the elements of the claimed invention are found in the prior art. Tr. 23-24. Therefore, the objective evidence regarding commercial success cited by the Patent Owner does not overcome the strong case of obviousness established by Petitioner by a preponderance of the evidence.

2. *Long-Felt but Unresolved Need for the Invention of the '070 Patent*

Patent Owner argues that a long-felt but unresolved need for the invention of the '070 patent indicates the non-obviousness of the claims of '070 patent. Resp. 58. Specifically, Patent Owner contends that Petitioner admits in its own document that there was a long-felt but unresolved need for the invention of the '070 patent. *Id.* Patent Owner cites to a marketing brochure from Petitioner, which states:

With significant investments into research and development over the years, *Endo GIA Reloads with Tri-Staple Technology and ENDO GIA Ultra Universal staplers have been developed with intent to fulfill the unmet needs of surgeons across different surgical specialties.* Covidien's revolutionary new Endo Stapling system enables surgeons to operate with confidence to handle a broader range of tissue thickness and applications with outstanding clinical performance.

Id. (citing Ex. 2020) (emphasis in original).

Mr. Ortiz, expert for Patent Owner, testified there was an unmet need for a stapling device that “enables surgeons to operate with confidence to handle a broader range of tissue thickness and applications with outstanding clinical performance.” Ex. 2004 ¶ 142. According to Patent Owner, this “unmet need was satisfied with a device that included a ‘fixed anvil’ and ‘improved tissue clamping’ (resulting from the use of different preformed and formed non-parallel staples) – all as required by the claims of the '070 Patent.” Resp. 59 (citing Ex. 2004 ¶ 144).

Petitioner contends the long-felt need of surgeons that is satisfied by the Tri-Staple devices is not attributable to the claimed features, but instead may be due to unclaimed features, such as ergonomic design, precise

articulation, and reloads that provide simpler selection and reduced inventory. Reply 15.

Satisfaction of a long-felt but unresolved need is not evidence of nonobviousness, unless it is shown that widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem. *In re Allen*, 324 F.2d 993, 997 (CCPA 1963); *Toledo Pressed Steel Co. v. Standard Parts, Inc.*, 307 U.S. 350, 356 (1939). Patent Owner has not directed our attention to evidence that there was a widespread attempt by skilled workers in the art for a long period of time to use non-parallel staples with different pre-formed heights to create staples with different formed heights, and that all such attempts failed to achieve successful use of such staples.

Furthermore, even if we consider Petitioner's brochure to be an admission against interest, the brochure fails to establish the existence of a "long-felt and unresolved" need in the industry, because it does not indicate that the "unmet need" is a persistent one recognized by those of ordinary skill in the art. *See In re Gershon*, 372 F. 2d 535, 539 (CCPA 1967). Thus, Petitioner's brochure does not support the assertion that there was a long-felt but unresolved need in the industry for Patent Owner's invention.

Therefore, we find that Patent Owner's arguments concerning the long-felt but unresolved need for the invention of the '070 patent do not overcome Petitioner's showing of obviousness.

III. CONCLUSION

We have considered the record before us in this *inter partes* review proceeding. We conclude that Petitioner has met its burden of proof, by a preponderance of the evidence, in showing that:

(1) claims 1-5, 7, 8, and 10-13 of the '070 patent are unpatentable under 35 U.S.C. § 103(a) over Viola and Green;

(2) claims 6, 11, and 14 of the '070 patent are unpatentable under 35 U.S.C. § 103(a) over Viola, Green, and Pruitt;

(3) claim 9 of the '070 patent is unpatentable under 35 U.S.C. § 103(a) over Viola, Green, and Burdorff;

(4) claims 8 and 10-14 of the '070 patent are unpatentable under 35 U.S.C. § 103(a) over Pruitt and Green;

(5) claim 9 of the '070 patent is unpatentable under 35 U.S.C. § 103(a) over Pruitt, Green, and Burdorff; and

(6) claims 1-7 of the '070 patent are unpatentable under 35 U.S.C. § 103(a) over Pruitt, Green, and Conta.

This is a final written decision.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1-14 of the '070 patent are determined to be UNPATENTABLE;

FURTHER ORDERED that because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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Patent 8,317,070

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